

REMARKS

Claims 67, 69, 70, 73, 79, 80, 82 and 98-101 are pending in this application, with Claim 67 being the sole independent claim. Claims 67, 69, 73, 79, 80 and 82 have been amended herein. Claims 1-66, 68, 71, 72, 74-78, 81, 83-97 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. Claims 98-101 have been newly added. The Abstract and the first paragraph of page one of the disclosure have been amended. All amendments presented herein are made for reasons of clarity with respect to the specification and drawings, and not for reasons relating to the statutory requirements for patentability.

In response to the requirement set forth in the Office Action, Applicant submits herewith a new Declaration in compliance with 37 CFR § 1.67(a), including a reference to the PCT priority application. However, Applicant claims priority from that PCT application under 35 U.S.C. § 120, and not under § 119 as indicated in the Office Action, as that PCT application was filed designating the United States. (See 35 U.S.C. §§ 120, 363.)

Applicant has replaced the old Abstract with a new Abstract having reduced length, and without legal phraseology, as required by the Office Action. Applicant has also amended the first paragraph on page 1 of the specification to reflect the status of the parent application.

Claim 67 has been amended to define the sample set as comprising plasma, serum, synovial fluid, cerebrospinal fluid, urine, mucus, lymphatic fluid, feces, semen, milk, cheese, cottage cheese, yogurt, ice cream, wine, beverages, semi-solid foods, soft solid foods, and any combination thereof. Furthermore, Claim 67 has been amended to indicate that one or more substances mimic two or more analytes within these samples. Support for these amendments may be found throughout the disclosure, and at least on page 22, bottom paragraph, and page 11, last sentence of the first paragraph. Claim 67 has also been amended to indicate that the quality control material is stabilized.

Support for this amendment may be found at least on page 22, first full paragraph, and page 42, last paragraph. Claims 69, 70, 73, have been amended to be consistent with the amendments made to Claim 67.

Support for new Claims 98-101 may be found in the claims as originally filed.

Rejections under 35 U.S.C. § 112

Claims 67, 69, 70, 75, 76 and 96 were rejected under 35 U.S.C. § 112, second paragraph, on the grounds that the phrase “wherein one or more analytes” in Claim 67 is indefinite. The Office Action suggests that the term “analyte” be replaced with the term “substance”. Applicant respectfully disagrees. The term “analyte” is defined in the specification as meaning a substance that is measured in a sample. This definition may be found on the last line of page 20 of the disclosure where it states that: “By analyte it is meant a substance being measured in a sample.”

Claim 69 was also rejected under 112, second paragraph, as being indefinite for depending from a cancelled claim. Claim 69 has been amended so that it now depends from Claim 67. Claim 75 was also rejected under 112, second paragraph, as being indefinite for repeating various analytes twice within the claim. Claim 75 has been cancelled without prejudice to or disclaimer of the subject matter contained therein.

Based on the amendments and remarks set forth herein, withdrawal of the rejections of Claims 67, 69, 70, 75, 76 and 96 under 35 U.S.C. § 112 is respectfully requested.

Obviousness-Type Double Patenting Rejection

Claims 67, 69-71, 73, 75, 79 and 80 were rejected under the judicially created doctrine of obviousness-type double patenting in view of Claims 1, 3, 4, and 10-12 of U.S. Patent No. 6,372,503.

Applicant submits that U.S. Patent No. 6,372,503 and the present application are commonly owned, and an executed Terminal Disclaimer and Assignment document are included herewith. Applicant therefore respectfully requests that this rejection be withdrawn.

Rejections under 35 U.S.C. § 102

Claims 67, 69-83 and 96 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by EP 0 132 399 (Campbell et al.). Applicant respectfully traverses this rejection.

Claim 67 has been amended to indicate that the quality control material comprises one or more substances that mimic two or more analytes in a defined sample set that does not include whole blood. Applicant submits that Campbell et al. disclose the use of one substance for monitoring one analyte in whole blood. Claims 71, 72, 74-78, 81 and 96 have been cancelled without prejudice or disclaimer. Furthermore, Claims 69, 70, 73, 79, 80 and 82 all depend ultimately from Claim 67, and include the features of the base claim. Applicant therefore submits that this grounds of rejection has been overcome.

Claims 67, 79 and 80 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,278,073 (Grandjean). Applicant respectfully traverses this rejection.

As noted above, Claim 67 has been amended to indicate that the quality control material comprises one or more substances that mimic two or more analytes in a defined sample set. Grandjean discloses the use of one substance to mimic one analyte, bilirubin. Claims 79 and 80 depend ultimately from Claim 67, and include the features of the base claim. Applicant therefore submits that this grounds of rejection has been overcome.

Claims 67, 79 and 80 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by U.S. Patent No. 5,310,679 (Artiss et al). Applicant respectfully traverses this rejection.

As noted above, Claim 67 has been amended to indicate that the quality control material comprises one or more substances that mimic two or more analytes in a defined sample set. Artiss et al. discloses the use of two substances to mimic one analyte, turbidity. Claims 79 and 80 depend ultimately from Claim 67, and include the features of the base claim. Applicant therefore submits that this grounds of rejection has been overcome.

Claims 67, 75-78, 80 and 81 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,116,336 (Sorensen). Applicant respectfully traverses this rejection.

Sorensen discloses the use of one substance to mimic one analyte, total hemoglobin. Claim 67 as presently amended specifies that the quality control material comprises one or more substances that mimic two or more analytes in a sample. Claim 80 depends from Claim 67 and includes the features of Claim 67. Furthermore, Claims 75-78 and 81 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. Applicant therefore submits that this grounds of rejection has been overcome.

Claims 67, 69-81, and 96 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by either of U.S. Patent No. 5,846,492 (Jacobs), or U.S. Patent No. 6,013,528 (Jacobs). Applicant respectfully traverses this rejection.

Jacobs discloses calibrator materials to be used for the development of calibration algorithms in a spectroscopic apparatus (e.g., see Column 9, lines 40-43 of U.S. Patent No. 6,013,528). The materials disclosed in Jacobs do not mimic analytes in a sample as claimed in the present invention, as the materials disclosed in Jacobs

contain the analytes used to develop the calibration algorithms. Furthermore, the substances used in the calibrator materials of Jacobs have a short shelf life, typically on the order of hours, rather than the long shelf life of the materials of the presently claimed invention, which may last for months to years. To further emphasize these differences, Claim 67 has been amended to indicate that the quality control material is stabilized. Claims 69, 70, 73, 79, 80 and 96 ultimately depend from Claim 67, and include the features of Claim 67. Furthermore, Claims 71, 72, 74-78 and 81 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. Applicant therefore submits that this grounds of rejection has been overcome.

Claims 67, 69-81, and 96 stand rejected under 35 U.S.C. 102(b) as being anticipated by US Application No. US 2003/0068822 (Jacobs). Applicant respectfully traverses this rejection.

The Jacobs publication discloses a control and calibrator material comprising one substance, a cross-linked blood substitute (see para. [0015]), that mimics one analyte. Jacobs does not disclose one or more substances that mimic two or more analytes as set forth in Claim 67. Claims 69, 70, 73, 79, 80 and 96 depend from Claim 67, and include the features of Claim 67. Furthermore, Claims 71, 72, 74-78 and 81 have been cancelled without prejudice to or disclaimer of the subject matter contained therein. Applicant therefore submits that this grounds of rejection has been overcome.

Based on the amendments and remarks set forth above, Applicant respectfully requests that the rejections under 35 U.S.C. § 102 be withdrawn.

Conclusion

It is respectfully submitted that the above-identified application is now in a condition for allowance, and favorable reconsideration and prompt allowance of these claims are respectfully requested. Should the Examiner believe that anything further is desirable in order to place the application in better condition for allowance, the

Examiner is invited to contact the applicant's undersigned attorney at the telephone number listed below.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202)625-3549. All correspondence should continue to be directed to our address given below.

Respectfully submitted,



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